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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,518

07/10/2003

Takeaki Nakamura

16809

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23389 7590 12/23/2008  
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EXAMINER

LANG, AMY T

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/616,518	<b>Applicant(s)</b> NAKAMURA ET AL.	
	<b>Examiner</b> AMY T. LANG	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 14, 18, 21, 28 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 14, 18, 21, 28, and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 14, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirt (US 2002/0010486 A1) in view of Woloszko et al. (US 2001/0025177 A1).

Hirt discloses a device for removing calculi having dual concentric probes. The outer probe is an ultrasonic probe driven by an ultrasonic horn and transducer. The inner probe is driven electro-magnetically to reciprocate to impact the calculi. Both probes are hollow and allow for aspiration of calculi particles there through. The abstract indicates that there is a switch (driving control device) which can change which probe is individually actuated by the appropriate drive circuitry. One circuit- 9-13 operates to activate the ultrasonic probe. The other circuit would then be inherent in an

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electromagnetic drive or rendered obvious. As disclosed in col. 21, it is clear that the two probes can be manufactured as different subassemblies, further indicating that the two probes are driven independently of each other. Suction port 19 communicates with the inner lumen of outer probe. See para. 12, 13 and 15.

Hirt teaches wherein the inner probe (20) is disposed within the outer probe (8) so that one probe lies coaxially within the other. This structure clearly overlaps the instantly claimed cylindrical-shaped tube structure divided in the longitudinal direction. Dividing a cylindrical tube lengthwise into an inner and outer cylinder along the longitudinal axis forms two coaxial tubes.

Hirt does not disclose the two probes as having a C-shaped cross section.

Woloszko et al. (hereinafter Woloszko) discloses that C-shaped probes are well known in the art ([0109]; Figure 11). Claim 105 teaches it is obvious to use different shaped probes including C-shaped probes. Additionally, the C-shaped forms ends (204, 206) that advantageously produce sharp edges and facilitate tissue cutting capabilities ([0109]). Therefore, in view of the teachings by Woloszko, it would have been obvious to one of ordinary skill in the art at the time of the invention for the probes of Hirt to comprise a C-shape cross section. The probes would then form a circular shape when the probes are aligned together.

4. Claims 28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirt (US 2002/0010486 A1) in view of Woloszko (US 2001/0025177 A1) as applied to claims 1 and 21 above, and further in view of Du et al. (US 2004/0127925 A1).

Hirt in view of Woloszko discloses the invention as claimed with the exception of the output setting units. However, Du discloses that it was known to provide a generator which can drive the actuator at desired frequencies ([0011]). It would have been obvious to provide a variable generator for both drive signals in order to tailor the movement of the probes to the specific calculi being disintegrated.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 1, 14, 18, 21, 28, and 31 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12/17/2008  
/Amy T Lang/  
Examiner, Art Unit 3731

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3731